

REMARKS AND ARGUMENTS

Initially, Applicant's attorney wishes to thank the Examiner for the careful attention given the present application. Claims 9, 15, and 22 are amended. Claims 1-8, 23 and 24 are cancelled. Claim 25 is new. Support for new claim 25 may be found in at least page 3, lines 28-31 of the specification, which discloses a pharmaceutical composition comprising antiproliferative and antiviral proteins and peptides.

Currently, claims 9-22, and 25 are pending in the present application. Applicant addresses each of the rejections set forth in the Office Action below.

35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 15-21 under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter regarded as the invention. Claim 15 has been amended and reconsideration and allowance is respectfully requested in view of the amendments and the following remarks.

The Examiner alleges that claim 15 would not enable one of skill in the art to practice the invention. Specifically, the Examiner has taken the position that the phrase "*effective amount*" is unclear because the effective amount is targeted to "inhibiting the effects of a viral infection" rather than inhibiting proliferation of the virus. Claim 15 has been amended to more clearly indicate that "an effective amount" is meant to read on *the proliferation* of a viral infection. Support for the anti-infective (antiviral) activity of the therapeutic composition may be found on at least page 14, in Tables I-V, and in Figure 4. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the Examiner's rejections of claims 15-21.

35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-24 under 35 U.S.C. § 112, first paragraph for purportedly failing to comply with the written description requirement. Applicant respectfully disagrees.

(A) The Examiner states that the genus of proteins of the therapeutic composition claimed by the Applicants is "highly variant because it does not limit the organs or species used to obtain the extract". Further, the Examiner states that "the art recognizes that embryonal extracts from different organ systems provides fractions having differing activities".

Claims 9 and 15 have been amended to recite the administration of specific isolated peptides, not the embryonal extract of cancelled claim 1. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the Examiner's rejections of claims 9-21.

(B) The Examiner indicates that the genus of peptides of Claim 22 is highly variant because it may include members which are minimally 7 amino acids and exhibit anti-proliferative activity. Applicant has amended claim 22 to more clearly indicate that the claim is directed to a peptide, as a compound, and use of the phrase "having" indicates that the compound itself is limited to the defined sequence; that is, the claim encompasses the recited sequence and does not encompass any larger or smaller sequence. Support for use of the term "isolated" in this amendment may be found in at least page 3, lines 23-27 of the specification. New claim 25 has been added to specifically claim a composition which contains an isolated peptide of SEQ ID. Nos. 1-12 and an excipient. Support for new claim 25 may be found in at least page 3, lines 28-31 of the specification. Accordingly, reconsideration and withdrawal of Examiner's rejection of claim 22 is respectfully requested in view of the amendment.

The Examiner indicates that claims 15-21, drawn to inhibiting *the effects* of a viral infection, is not adequately described. Claim 15 has been amended to more clearly indicate that the inhibition is of *the proliferation* of a viral infection. Support for the anti-infective (antiviral) activity of the therapeutic composition may be found on at least page 14, in Tables I-V, and in Figure 4. Accordingly, Applicant's respectfully request reconsideration and withdrawal of the Examiner's rejections of claims 15-21.

The Examiner indicates that claim 22 and 23, drawn to a method for inhibiting the proliferation of cancer cells by a peptide of SEQ ID Nos. 1-12, is not enabled by the specification as only SEQ ID Nos. 2, 3 and 8 have such activity. Claim 23 has been canceled, thus rendering Examiner's rejection moot. It is respectfully submitted that claim 22 is directed to the isolated peptides and, as a composition claim, does not include any activity recitation. Claim 24 has been canceled. Accordingly, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection of claim 22.

35 U.S.C. § 102(e)

Barnea U.S. Patent No. 5,648,340

The Examiner has rejected claims 22-24 under 35 U.S.C. § 102(e) as allegedly being anticipated by Barnea in U.S. Patent No. 5,648,340 (hereinafter "the '340 patent"). The Examiner has taken the position that the anti-proliferative fraction of the '340 patent would inherently comprise peptides of SEQ ID Nos. 1-12 of Applicant's invention because the origin of the material is the same. Claim 23 has been canceled, thus rendering Examiner's rejection moot. Claims 22 and 24 have been amended to read on *isolated* peptides of the sequences listed. This differs from the '340 patent, which discloses a cell fraction with anti-proliferative activity. The cell fraction contains a combination of the peptides, proteins, small molecules, and any other components having a molecular weight less than 8,000 daltons that are found within a cell extract. Accordingly, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection of claims 22 and 24.

35 U.S.C. § 102(b)

Barnea U.S. Patent No. 5,648,340

The Examiner has rejected claims 9-11, 13 and 14 under 35 U.S.C. § 102(b) as allegedly being anticipated by the '340 patent. The Examiner has taken the position that the high molecular weight anti-proliferative fraction of the '340 patent would anticipate the therapeutic composition of Applicant's instant invention because the origin of the material is the same. Claim 9 has been amended to read on a set of *isolated* peptides of the sequences listed. This differs from the '340 patent, which discloses a cell fraction with anti-proliferative activity which contains a combination of the peptides, proteins, small molecules, and any other components having a molecular weight less than 8,000 daltons that are found within a cell extract. Accordingly, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection of claims 9-11, 13 and 14.

Barnea, et al., American Journal of Reproductive Immunology, 1996, Vol. 35, pp. 318-324

The Examiner has rejected claim 22 under 35 U.S.C. § 102(b) as allegedly being anticipated by Barnea, *et al.*, American Journal of Reproductive Immunology, 1996, Vol. 35, pp.

318-324 (hereinafter "Barnea-1996"). The Examiner has taken the position that the anti-proliferative fraction of Barnea-1996 would inherently comprise peptides of SEQ ID Nos. 1-12 of Applicant's invention because the origin of the material is the same. Applicants respectfully disagree. Claim 22 has been amended to read on *isolated* peptides of the sequences listed. This differs from Barnea-1996, which discloses a cell fraction with anti-proliferative activity. The cell fraction contains a combination of the peptides, proteins, small molecules, and any other components having a molecular weight less than 8,000 daltons that are found within a cell extract. Accordingly, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection of claim 22.

Cavanaugh, et al., in U.S. Patent No. 5,393,534 in view of Brill, et al., Proceedings of the Society for Experimental Biology and Medicine, 1993, Vol. 204, pp. 261-269

The Examiner has rejected claims 1-3 and 6 under 35 U.S.C. § 102(b) as allegedly being anticipated by Cavanaugh, *et al.*, in U.S. Patent No. 5,393,534 (hereinafter "Cavanaugh") in view of Brill, *et al.*, Proceedings of the Society for Experimental Biology and Medicine, 1993, Vol. 204, pp. 261-269 (hereinafter "Brill"). Applicants have cancelled claims 1-8, thus rendering Examiner's rejection moot.

35 USC § 103(a)

Cavanaugh

The Examiner has rejected claims 9-11 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Cavanaugh. The Examiner states that "Cavanaugh *et al.* teach a protein prepared from an extract of liver homogenate, said extract having a growth inhibitory effect ... which fulfills the specific embodiment of claims 1-3 and 6". Claim 9 has been amended to read on a set of *isolated* peptides of the sequences listed. This differs from Cavanaugh, which discloses a cell fraction with anti-proliferative activity which contains a combination of the peptides, proteins, small molecules, and any other components having a molecular weight of between 38 and 42 kDa that are found within a cell extract. Accordingly, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection of claims 9-11 and 13.

Ajinomotot, Biotech on STN, The Thompson Corp. JP 60178820, September 12, 1985 in view of Barnea-1996.

The Examiner has rejected claims 1 and 2 under 35 U.S.C. § 103(a) as being unpatentable over the abstract of Ajinomotot, Biotech on STN, The Thompson Corp. JP 60178820, September 12, 1985 (hereinafter "Ajinomotot") in view of Barnea-1996. Applicants have cancelled claims 1-8, thus rendering Examiner's rejection moot.

CONCLUSION

It is believed that the pending claims are in condition for allowance and notice to such effect is respectfully requested. The Commissioner is hereby authorized to charge deposit account No. 50-0436 for any additional fees that may be due in connection with this response.

Should the Examiner have any questions regarding this application, the Examiner is invited to initiate a telephone conference with the undersigned.

Respectfully submitted,

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